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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,100	01/09/2006	Sarah C. Bodary	P1977R1	3801
9157	7590	09/19/2006	EXAMINER	
GENENTECH, INC. 1 DNA WAY SOUTH SAN FRANCISCO, CA 94080			LEAVITT, MARIA GOMEZ	
			ART UNIT	PAPER NUMBER
			1633	
DATE MAILED: 09/19/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/527,100	Applicant(s) BODARY ET AL.	
	Examiner Maria Leavitt	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

DETAILED ACTION

Election/Restrictions

Claims 1-28 are pending in the present application, and they are subjected to the following restrictions.

*Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Claims 1, 2, 3, and 9 embrace a very large number of sequences for search and examination. The amendment to the original claims comprising the computer readable copy of the Sequence Listing entitled, " P1977R1" was filed on 01-09-2006, after the filing date of the Specification, date of filing 03-09-2005. There is not disclosure in the as-filed Specification as to the correlation of these sequences. Moreover, the instant claims are drawn to nucleotide sequences having at least 80% homology with the disclosed sequence ID Nos:1-106. Therefore, sequence ID Nos:1-106 and variants are interpreted as distinct from each other, coding for a polypeptide having different chemical structures, physical properties, and biological functions as a result of containing different genes, which required separate searches.

Applicant is required to select one specifically named sequence from:

- I. A nucleotide sequence of claim 1- 3 and 9.
- II. A chimeric molecule comprising a polypeptide as recited in claims 1-3 and 9.
- III. An antibody against a polypeptide sequence as recited in claim 1-3 and 9.
- IV. An agonist of said polypeptide polypeptide sequence as recited in claim 1-3 and 9.
- V. An antagonist of said polypeptide polypeptide sequence as recited in claim 1-3 and 9.

The technical feature linking Groups I to V appears to be a nucleic acid sequence that are differentially expressed in diseased tissue relative to normal tissue. However, sequences of isolated polynucleotides and/or genes and/or polypeptides from test samples of diseases derived from cancer, cardiovascular disease, and neurological disease have no substantial common core structures one from the others. Since these nucleic acid sequences and their portions have different nucleotide sequences one from the others, and each nucleotide sequence becomes a basis for the “special technical feature” for that Group and not required for the other Groups, the currently claimed subject matter lacks unity of invention according to Rule 13.1 PCT.

Because the currently claimed subject matter lacks unity according to Rule 13.1 PCT for the reasons set forth above, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Should a group drawn to a specifically named SEQ ID No. be elected, restriction is further required under 35 U.S.C. 121 and 372.

Group VI, claims 1, 2, 3, 4-8, 9, 18-19 drawn to an isolated nucleic acid encoding the polypeptide, a recombinant expression vector comprising said sequence, a host cell comprising said vector, a process for producing said polypeptide using said host cell and said isolated polypeptide and a method for treating an immune related disorder in a mammal by administering said polypeptide.

Group VII, claims 9-11, 14-16, and 17 drawn to an isolated polypeptide, a chimeric molecule comprising said polypeptide, a composition and an article of manufacture comprising said polypeptide.

Group VIII, claims 12-16 and 17 drawn to an antibody, which specifically binds a polypeptide, a composition comprising and an article of manufacture comprising said antibody.

Because the currently claimed subject matter lacks unity according to Rule 13.1 PCT for the reasons set forth above, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Claims 20, 21, 22, 23, 24, 26-28 are drawn to methods embracing a very large number of sequences for search and examination. The amendment to the original claims comprising the computer readable copy of the Sequence Listing entitled, " P1977R1" was filed on 01-09-2006, after the filing date of the Specification, date of filing 03-09-2005. There is not disclosure in the as-filed Specification as to the correlation of these sequences. Therefore, genes encoding PRO polypeptides of claims 20, 21, 22, 23, 24, 26-28 are interpreted as distinct from each other, coding for a polypeptide having different chemical structures, physical properties, and biological functions as a result of containing different genes, which required separate searches.

Applicant is require to select one specifically named sequenced of a PRO polypeptide from:

IX. A method comprising the presence of a PRO polypeptide.

X. A method comprising the presence of gene encoding a PRO polypeptide

XI. A method comprising the presence of an anti PRO polypeptide antibody

XII. A method comprising the presence of an inhibitor of a gene encoding a PRO polypeptide

XIII. A method comprising the presence of an antagonist of a PRO polypeptide

The technical feature linking Groups IX to XIII appears to be a method comprising a nucleic acid sequence that are differentially expressed in diseased tissue relative to normal tissue. However, sequences of isolated polynucleotides and/or genes and/or polypeptydes from test samples of diseases derived from cancer, cardiovascular disease, and neurological disease have

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no substantial common core structures one from the others. Since these nucleic acid sequences and their portions have different nucleotide sequences one from the others, and each nucleotide sequence becomes a basis for the “special technical feature” for that Group and not required for the other Groups, the currently claimed subject matter lacks unity of invention according to Rule 13.1 PCT.

Because the currently claimed subject matter lacks unity according to Rule 13.1 PCT for the reasons set forth above, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Should a group drawn to a method comprising a specifically named SEQ ID No. be elected, restriction is further required under 35 U.S.C. 121 and 372.

Group XIV, claims 20 and 22 drawn to a method for determining the presence of a PRO polypeptide by contacting a sample with an antibody selected from the Markush group of claim 20.

Group XV, claims 21 and 28 drawn to a method for diagnosing an immune related disease in a mammal detecting the level of a gene using a nucleic acid probe.

Group XVI, claims 23 drawn to a method for diagnosing an immune related disease in a mammal, by using a polypeptide.

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Group XVII, claims 24-26 drawn to a method for identifying a compound using cell expressing he polypeptide.

Group XVIII, claims 27 drawn to a method for stimulating an immune response using a polypeptide agonist.

Because the currently claimed subject matter lacks unity according to Rule 13.1 PCT for the reasons set forth above, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Species Restriction.

Should Groups VI be elected, a species restriction is further required under 35 U.S.C. 121 and 372, wherein a species election(s) must correspond to an elected group as indicated above.

This application contains claims directed to the following patentably distinct species:

This application contains claims directed to the following patentably distinct species:

Immune related disorders.

1) Applicant is required to choose one specifically named Immune related disorders as recited in claim 19.

The species are independent or distinct because there drawn to diseases having different biological functions as a result of containing different expressed genes.



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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776 or the examiner's supervisor, Nguyen Dave, can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

To aid in correlating any papers for this application, all further correspondence regarding his application should be directed to Group Art Unit 1636; Central Fax No. (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also

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enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

Maria Leavitt, PhD  
Patent Examiner P/1633  
Remsen 2B55  
Phone: 571-272-1085  
Email: [maria.leavitt@uspto.gov](mailto:maria.leavitt@uspto.gov)

A handwritten signature in black ink, appearing to read 'Dave', with a long, sweeping horizontal line extending to the right.

**DAVE TRONG NGUYEN**  
**SUPERVISORY PATENT EXAMINER**